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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Erik J. van der Burg

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS

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EXAMINER

BATES, DAVID W

ART UNIT

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3775

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/736,457	Applicant(s) VAN DER BURG ET AL.	
	Examiner DAVID W. BATES	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-32 and 46-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 27-32 and 46-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 30 is objected to because of the following informalities: the word "comprises" has been deleted from the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 27-32 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 27-32 fail to correspond in scope with that which applicants regard as the invention can be found in the reply filed April 5, 2010. In that paper, applicant has stated that the lock has failed to either fix *the* relationship between the attachment zones or inhibit *the* movement between first and second attachment zones. This statement indicates that the invention intended is different from that which is defined in the claim. The claim states that there is a connection between the first and second attachment zones which allows movement of the first and second attachment zones with respect to one another. In conjunction with that limitation, Applicant's claim clearly cannot require that the lock prevents *all* movement between the attachment zones at the same time, as is presently claimed. Arguing that he has taught such is contrary to the claimed invention. It is suggested that applicant needs to include a sequential limitation to the claim - e.g. "when locked".

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 27-32, and 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakajima (US 6,355,036 B1).

6. Regarding claims 27, 29-32, and 46, Nakajima teaches:

An implant for attachment to a hyoid bone (a bone adjuster 20, attached to bone in fig. 4), **comprising:**

an implant body (lift plate 22);

a first attachment zone (mounting plate 28) **configured for attachment to a first portion of a hyoid bone;**

a second attachment zone (mounting plate 42) **configured for attachment to a second portion of a hyoid bone;**

a connection between the first and second attachment zones (at hinge 36, the connection is formed due to all components being "connected to one another") **which allows movement of the first and second attachment zones with respect to each other; and**

a lock carried by the body (adjusting shaft 26), **for inhibiting the movement between the first and second attachment zones** (prevents movement between the attachment zones in at least one axis).

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from

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a prior art apparatus satisfying the claimed structural limitations. The attachment assembly of Nakajima is capable of use in any bone in the body by simple changes to the embodiment disclosed (change in size/orientation, col. 7, lines 52-62).

7. Regarding claim 28, the hinge 36 is capable of bending, and is therefore considered to be “flexible”.

8. Regarding claims 47-49, the description of the type of pharyngeal structure the implant is used in is regarded as being merely a recitation with respect to the manner in which the claimed apparatus is intended to be employed and does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. The device of Nakajima is capable of being used in such situations as bone and muscle by use of different connection devices in conjunction with the device (screws, cerclage wires, tacks, sutures, etc.).

9. Claims 27-32 are alternately rejected and claims 50, 51 and 58-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackson (US 6,685,742 B1).

10. Regarding claims 27-32, 50, 51 and 58-61, Jackson teaches:

An implant for attachment to a hyoid bone (intended use, the implant can be attached to the bone by being expanded outwardly by use of the driver 11 to meet two sides of the bone), **comprising:**

an implant body (assembly of fig. 1);

a first attachment zone (first leg 12) **configured for attachment to a first portion of a hyoid bone;**

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a second attachment zone (second leg 13) configured for attachment to a second portion of a hyoid bone;

a connection (bearing 14) between the first and second attachment zones which allows movement (pivotal around P) of the first and second attachment zones with respect to each other; and

a lock carried by the body (driver 11), for inhibiting the movement between the first and second attachment zones.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima.

13. Nakajima discloses the claimed invention except that Nakajima teaches use of a hinge as a pivot joint instead of a 1) ball and socket joint, 2) joint comprising wires, 3) joint comprising a ribbon, or a 4) clevis pin. These are known to be obvious variants of an equivalent structure in the art. Therefore, because these joint means were art-recognized equivalents which accomplish the same result at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute any of the means of pivoting (1) – (4) for the hinge of Nakajima.

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14. Claims 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson.

15. Jackson discloses the claimed invention except that Jackson teaches use of a hinge as a pivot joint instead of a 1) ball and socket joint, 2) joint comprising wires, 3) joint comprising a ribbon, or a 4) clevis pin. These are known to be obvious variants of an equivalent structure in the art. Therefore, because these joint means were art-recognized equivalents which accomplish the same result at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute any of the means of pivoting (1) – (4) for the hinge of Jackson.

Response to Arguments

16. Applicant's arguments filed April 5, 2010 have been fully considered but they are not persuasive. Applicant argues that the lock, as cited in the Nakajima reference, fails to either "fix *the* relationship" or "inhibit *the* movement" between the attachment zones. By this, applicant means that the lock is capable of adjusting only one dimension between the attachment zones and has not fixed the attachment zones relative to one another.

17. Examiner will agree with applicant's assessment of the Nakajima patent. Examiner will, however, disagree that this difference differentiates the *claimed* invention from the prior art.

18. Claims 27 and 46 require a connection which allows movement between two attachment zones, and a separate lock which either inhibits the movement between the attachment zones, or fixes the relationship between the contact zones.

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19. Initially, if applicant is trying to state that the lock is *only* inhibiting *the* movement which was allowed by the connection, this is unclear as claimed. Applicant will need to claim that the connection allows a movement to make it clear that the movement being inhibited is antecedent to the first movement. Currently, *the movement between the connection zones* is interpreted to be any movement between the connection zones. Inhibiting any movement between the connection zones reads upon the claim.

20. The claim states that there is a connection between the first and second attachment zones which allows movement of the first and second attachment zones with respect to one another. In conjunction with that limitation, Applicant's claim clearly cannot both require that the lock prevents *all* movement between the attachment zones and allow movement. It is suggested that applicant needs to include a sequential limitation to the claim - e.g. "when locked".

21. The arrangement of Nakajima has both inhibited the movement between the first and second attachment zones (toward and away from one another) and fixed the relationship between them (toward and away from one another) while allowing movement at the connection, as required in the claims.

22. Further, as intended to be used, Nakajima will be implanted against bone. When implanted in this fashion, the attachment zones will be fixed relative to one another based on the attachment to the bone.

23. Further, viewing fig. 4 of Nakajima, the lock (shaft 26) will serve to prevent the rotational component of the movement of the device at at least some angles (the

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pivoting motion is prevented from going past horizontal by the portions of the shaft 26 which extend beyond portions 34 and 48.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Andrews (US 4,741,698) teaches an implant which has an interconnection between two attachment zones.
- Pisharodi (US 5,693,100) teaches an implant which has a locking mechanism and two movable legs. Seen best at figs. 5 and 6.

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DAVID W. BATES** whose telephone number is

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(571)270-7034. The examiner can normally be reached on Monday-Friday 9:00AM - 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. W. B./
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775